



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,099	03/02/2001	A. Michael Frace	98,506-C	1471
23859	7590	09/22/2004	EXAMINER	
NEEDLE & ROSENBERG, P.C. SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			LUCAS, ZACHARIAH	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 09/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

MS

Advisory Action

Application No.

09/485,099

Applicant(s)

FRACE ET AL.

Examiner

Zachariah Lucas

Art Unit

1648

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 20 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 90-101.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☒ Other: See Continuation Sheet

Continuation of 5. does NOT place the application in condition for allowance because:

The Applicant traverses the rejection of claims 90, 91, 93, 95, 96, and 98 as being unpatentable over Kendal in view of Black, and Spaete on the grounds that the teachings of the Spaete reference do not attribute the increased expression of the proteins to the deletion of the transmembrane (TM) domain, but to the coexpression of the protein with the deleted TM domain with an escort. However, this argument is not found persuasive.

The Applicant's argument is not found persuasive because, to whatever the reference attributes the increased expression, the reference nonetheless renders obvious the production of proteins through deletion of the TM domain. The fact that the reference teaches the use of a chaperone does not distinguish from the claimed invention because the claims are silent as to the present or absence of such chaperones. Further, regardless of the presence of the chaperone, the teachings of Spaete, in combination with the other references, render obvious the making of M2 antigen with a deleted TM domain. While the reference indicates that the chaperone must be present during the expression of the protein, such is not excluded by the claims in the present case. Further, the reference also teaches that the fusion of the chaperone and the expressed protein preferable comprises a cleavage site such that the chaperone is removed from the protein after expression. See e.g., column 13 lines 1-11, and col. 18 lines 35-49. Thus, the Applicant has not demonstrated that there is any structural distinction between the proteins suggested by the combination and the protein used in the claimed methods. Because such proteins meet the structural limitations of the claims, the references render obvious the claimed methods.

Based on the Applicant's arguments, it appears that the best argument that can be made is that the Applicant has discovered a previously unrealized benefit to the deletion of the TM domain. However, recognition of such additional advantages does not make the claimed invention non-obvious. See e.g., MPEP § 2145 II. Because the art provides both a suggestion and a motivation for combining the cited references, and because such a combination results in the claimed invention, the Applicant's arguments in traversal are not found persuasive.

The rejections of claims 90- 93, and 101, as being unpatentable over Kendal in view of Black and Spaete as applied to claim 90 above, and further in view of Anderson et al. (U.S. Patent 6,180,343), and of claim 94 over Kendal in view of Black, Spaete, and Anderson as applied to claims 90-93, and further in view of Ito et al. (J Virol 65: 5491-98) were traversed for the same reasons as asserted above. The rejections of these claims are therefore also maintained for the reasons above, and the reasons of record.

Claims 95, 97, and 99 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kendal in view of Black and Spaete as applied to claims 90, 91, and 93 above, and further in view of Kaplakis-Deliyannis et al., (Electrophoresis 14: 926-936), and Slepushkin et al., (Vaccine 13(15): 1399-1402- of record in the April 2000 IDS). The Applicant traverses this rejection on two grounds. First, the Applicant asserts that the two additional references do not suggest the use of MS proteins lacking the 12 amino acids on the C-terminal of the TM domain as immunogens, but rather indicates only that such proteins were detected by antibodies to the native M2 protein. From this, the Applicant concludes that there is no teaching that M2 proteins lacking these amino acids would be effective immunogens. However, as indicated in the prior action, the art establishes that the sequences lacking these residues are effective targets for anti-M2 antibodies, and identifies epitopes targeted by such antibodies that are outside of the deleted region. Both of these teachings indicate that polypeptides lacking the 12 residues at issue would be effective antigens.

Because the Examiner has presented evidence that those in the art would have expected the indicated M2 derivatives to be effective immunogens, more than a mere assertion of patentability is required. See e.g., MPEP 2145 I. However, the Applicant has presented no evidence to that contradict, or otherwise come to a conclusion other than is suggested by the teachings referred to above. In view of this lack of evidence, the Applicant's unsupported arguments are not found persuasive.

The Applicant's second argument in traversal is substantially the same as argued with respect to claims 90, 91, and 93 above. For the reasons indicated above, the second ground of traversal is also not found persuasive. The rejection is therefore maintained for these reasons, and the reasons of record.

Continuation of 10. Other: The Applicants arguments (that the present case is a 371 application filed from a PCT application filed prior to November 29, 2000) and amendments to the specification have overcome the objections to the claim to priority as being after the time period set forth in amended 37 CFR 1.78.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachariah Lucas whose telephone number is 571-272-0905. The examiner can normally be reached on Monday-Friday, 8 am to 4:30 pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system.

Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Z. Lucas
Patent Examiner


JAMES HOUSEL 9/20/04
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600